UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,348	02/24/2004	Susan Shelso	1001.1725101	8750

28075 7590 11/01/2006

CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NIT

Office Action Summary	Application No.	Applicant(s)	
	10/785,348	SHELSO ET AL.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,16,17 and 19-37* is/are pending in the application.

4a) Of the above claim(s) *3,24 and 29-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-12,16,17,19-23,25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is still unclear to the examiner what Applicant is trying to claim, despite the amended claim. Is Applicant trying to claim that the second region curves inward into the lumen to provide a rounded tip? Is it perhaps better to use the phrase, "curves distally along an axis"? It is unclear what Applicant means by along a radius, and it is unclear what radius Applicant is referring to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffin et al. (US 2003/0125751). Griffin discloses a medical device (Figs. 49 and 50) for slidable use with a guidewire (21), the guidewire having a first diameter and a distal stop having

a second diameter greater than the first diameter (Fig. 6a, 29; paragraph [0187] discloses that the guidewire has a stop on it), the medical device comprising: an elongate tubular member (Figs. 49 and 50, 210) having a proximal end (near 2) and a distal end (near 31) with a guidewire receiving lumen (7) extending therethrough, a distal portion of the guidewire lumen having an inner diameter of substantially the same magnitude as the first diameter (portion 13 clearly has a lumen within it that snugly encompasses the diameter of the guidewire); and a tip (the tip beginning at where the portion 13 ends and the tip extends distally until the very distal-most part of 202) defining an annular wall (the lumen which 21 passes through is an annular wall) disposed at the distal end of the elongate tubular member, the tip having a first portion having a distal taper (the tip tapers from its beginning to the tip at 202) and a radially inextensible ring distal of the first portion (202; see paragraphs [0266], [0267] and [0303]) wherein the annular wall of the tip has a thickness that decreases distally along a majority of the length of the tip (based on the definition of the tip defined above, the thickness of the tip decreases distally along the entire length).

In reference to claim 2, Griffin discloses that a therapeutic device (Fig. 6b, balloon 26) is disposed on the distal portion of the elongate tubular member.

In reference to claim 4, Griffin discloses that the first portion is softer and more flexible than a proximal portion of the medical device (Figs. 49 and 50 disclose that a hypotube (201) is used in the proximal portion of the medical device to stiffen it. Paragraphs [0266], [0267] and [0303] disclose that the first portion is a soft polymeric portion).

In reference to claim 5, Griffin discloses that the ring (202) is the distalmost portion of the tip (Figs. 49 and 50).

In reference to claim 6, Griffin discloses that the medical device is an angioplasty device (paragraph [0182]).

In reference to claim 7, Griffin discloses that the medical device is an intravascular filter (paragraph [0182]).

In reference to claim 8, Griffin discloses that the medical device is an intravascular guide catheter (paragraph [0070]).

Claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by Griffin et al. (US 2003/0125751). Griffin discloses a medical device (Figs. 49 and 50) comprising: an elongate catheter (210) having a proximal end (near 2) and a distal end (near 31), and a lumen (7) extending therethrough; and a tip (the tip beginning at where the portion 13 ends and the tip extends distally until the very distal-most part of 202) defining an annular wall (the lumen which 21 passes through is an annular wall) disposed at the distal end of the elongate catheter, the tip extending distally of the distal end of the catheter, the tip comprising a soft body portion (diagonally-lined portion 31) and a rigid ring (202) distal of the soft body portion (see paragraphs [0266], [0267] and [0303]), wherein the annular wall of the tip has a thickness that decreases distally along a majority of the length of the tip (based on the definition of the tip defined above, the thickness of the tip decreases distally along the entire length).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-12, 16, 17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (US 2003/0125751) in view of Muni et al. (US Patent No. 5,316,706). Griffin discloses a medical device (Figs. 49 and 50) for slidable use with a guidewire (21), the guidewire having a first diameter and a distal stop having a second diameter greater than the first diameter (Fig. 6a, 29; paragraph [0187] discloses that the guidewire has a stop on it), the medical device comprising: an elongate tubular member (210) having a proximal end (near 2) and a distal end (near 31) with a guidewire receiving lumen (7) extending therethrough, a distal portion of the guidewire lumen having an inner diameter of substantially the same magnitude as the first diameter (portion 13 clearly has a lumen within it that snugly encompasses the diameter of the guidewire); and a tip (the tip beginning at where the portion 13 ends and the tip extends

distally until the very distal-most part of 202) disposed at the distal end of the elongate tubular member and having a distal end (at 202), a proximal end (where 13 ends) and a lumen therethrough, the tip having an elastic portion (diagonally-lined portion 31) and a radially inextensible distal portion (202; also see paragraphs [0266], [0267] and [0303]). Griffin, however, does not disclose that the tip is made from an amorphous polymer and the distal portion from a crystalline section. Muni, however, discloses a catheter and method of making a catheter, in which softer sections are made from amorphous polymers and the hardened sections are made from crystalline sections (col. 3, lines 33-39 disclose the relationship between crystallinity and hardness, while col. 3, line 60 through col. 4, line 29 disclose that the crystalline and amorphous sections can be altered so that the catheter can have any pattern of hardness and softness). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin with the method and pattern of hardening catheter sections by altering crystallinity, as taught by Muni, in order to provide another source of a hardened tip for the catheter, especially since Griffin does not disclose the type of material that is used, other than a "relatively hard material" and a "soft polymeric material" (paragraphs [0266], [0267] and [0303]).

In reference to claim 10, Griffin discloses that the distal portion is an extremity (Figs. 49 and 50).

In reference to claim 11, Griffin discloses that the extremity is a distalmost extremity (Figs. 49 and 50).

In reference to claim 12, Griffin discloses that the distal portion comprises a ring (202) having a lumen therethrough.

In reference to claims 16 and 17, as defined by MPEP 2113, product by process claims are not limited to the recited steps, only the structure implied by the steps. Therefore the distal portion is anticipated by Griffin.

In reference to claim 19, Griffin discloses that the distal portion comprises a non-compliant band of material (paragraphs [0266], [0267] and [0303]), but Griffin does not disclose that it is a plastic band. However, since Griffin discloses that the distal portion is just a band of hard material, obvious that a noncompliant band of plastic would fit within this group and is thus an obvious possible material used by Griffin.

In reference to claim 20, Griffin discloses that the tip further comprises a flexible portion proximate the distal portion (diagonally-lined portion 31; also see paragraphs [0266] and [0267]).

In reference to claim 21, Griffin discloses that the distal portion is a distal most extremity (202 is the very distal-most portion) and wherein the flexible portion (diagonal-lined area 31) is proximal of the distal portion, wherein the flexible portion tapers from a first outer diameter at a first location along the tip to a second diameter less than the first outer diameter at a second location along the tip distal of the first location (the first location is where 13 ends, and this outer diameter tapers to a second diameter at the tip near 202 which is a smaller outer diameter).

In reference to claim 22, Griffin discloses that at the first location along the tip, the tip has a first thickness and a first inner diameter, and wherein at the second

location along the tip distal of the first location, the tip has a second thickness less than the first thickness and a second inner diameter greater than the first inner diameter (at the first location where 13 ends and the flexible portion 31 begins, there is a large thickness and an inner diameter that is similar to the diameter of the guidewire. At the second location at the tip near 202, the flexible portion has a much smaller thickness and the inner diameter of the flexible portion is larger since the ring (202) takes up room at the tip, and hence the flexible portion cannot surround the guidewire lumen).

In reference to claim 23, Griffin discloses that the flexible portion comprises an inner surface concave in a first plane normal to a longitudinal axis and a second plane normal to the first plane (Fig. 34 is an embodiment of the tip which demonstrates Griffin's anticipation of this shaped tip).

Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al. (US 2003/0125751) in view of Muni et al. (US Patent NO. 5,316,706). Griffin discloses a medical device (Figs. 49 and 50) comprising: an elongate catheter (210) having a proximal end (near 2), a distal end (near 31) and a lumen extending therethrough (7); a tip (the tip beginning at where the portion 13 ends and the tip extends distally until the very distal-most part of 202) disposed at the distal end of the elongate catheter having a first region that tapers distally (the first region is where the tip begins) and a second region distal of the first region that tapers distally more sharply than the first region (the second region is at 202, where the taper is so sharp that it extends downward to the opening of the lumen). Griffin, however, does not disclose that the first region comprises an amorphous polymer and that the second region

comprises a crystalline section thereof. Muni, however, discloses a catheter and method of making a catheter, in which softer sections are made from amorphous polymers and the hardened sections are made from crystalline sections (col. 3, lines 33-39 disclose the relationship between crystallinity and hardness, while col. 3, line 60 through col. 4, line 29 disclose that the crystalline and amorphous sections can be altered so that the catheter can have any pattern of hardness and softness). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Griffin with the method and pattern of hardening catheter sections by altering crystallinity, as taught by Muni, in order to provide another source of a hardened tip for the catheter, especially since Griffin does not disclose the type of material that is used, other than a "relatively hard material" and a "soft polymeric material" (paragraphs [0266], [0267] and [0303]).

In reference to claim 27, Griffin discloses that the second region is the distalmost portion of the tip (Figs. 49 and 50, 202 is the very tip).

In reference to claim 28, Griffin discloses that the second region curves distally along a radius (202 curves around the radius of the lumen it surrounds).

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4-12, 19-23, 25-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

LCS

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER